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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,530	10/10/2003	Lambertus Thijs	SYN-0033A	9721

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EXAMINER	
SACKEY, EBENEZER O	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/682,530	THIJS ET AL.	
	Examiner	Art Unit	
	EBENEZER SACKEY	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/14/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-31* is/are allowed.

6)☒ Claim(s) *32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/14/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

SBD

DETAILED ACTION

Status of Claims

Claims 1-32 are pending.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed 01/14/04 is acknowledged and has been entered into the file. A signed copy of the 1449 is attached herewith.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reactant of formula (3), does not reasonably provide enablement for the term "reaction partner". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claim 1 recites a method of preparing a bicalutamide of formula (I) comprising the step of reacting a p-fluorobenzenesulfinic acid of formula (2) with "a suitable reaction partner", then converting the obtained product to a bicalutamide.

Bicalutamides are known in the art and myriad methods for preparing various types can be found as evidenced by U.S.Patent numbers 6,300,514 and 4,636,505. Note in these patents the production of specific types of bicalutamide and specific reactants, not any and all reactants as alleged herein.

Applicants own specification, pages 11-12, the last paragraph of page 11 bridging page 12, recites only formula (3) suggesting the unpredictability of the process.

Also, given the conversion step needed to make the bicalutamide, not all the reaction partners would be considered viable groups, which are employed in the conversion step.

The specification provides no other guidance as to what other types of reaction partners are suitable for use in the instant process. Applicant's limited working

examples do not enable one of ordinary skill in the art to prepare any and all bicalutamide and employ any reaction partner encompassed by the instant invention.

Hence, the specification fails to provide sufficient support for the broad use of the term reaction partner, necessitating one of ordinary skill in the art to perform an exhaustive search for which particular reaction partner can be used in order to practice the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1.) The phrase "a suitable reaction partner " is of indeterminate scope". Applicants have recited a reactant without any specificity. The only specific reactant disclosed is formula (3).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 32 is rejected under 35 U.S.C. 102(e) as being anticipated by Dolitzky et al. (WO 02/100339 A2).

Applicants claim compounds of formula (4), wherein the substituents are as defined. Dolitzky et al., disclose substituted fluorophenyl sulfone compounds, which anticipates the instant compounds wherein A is OR, in which R is ethyl and X represents hydrogen. See example 1, page 7 and page 9, line 1.

Claim Rejections - 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

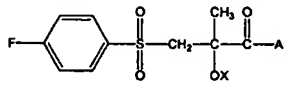
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi et al. (U.S.Patent number 6,300,514).

Applicants claim fluorobenzenesulfonyl compounds of structural formula (4), wherein substituents A represents OR, in which R is C_1-C_6alkyl and X represents hydrogen.



(4)

Determination of the scope and content of the prior art (MPEP §2141.01)

Takahashi et al., teach compounds structurally similar to the instantly claimed compounds. See column 188, Example 21, lines 50-60 and column 202, claim 10, compound (19), lines 3-4.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the claimed compounds and that of the reference herein lie in the selection of a different halogen on the forth position of the benzene ring, which is F in the claimed compounds instead of Br in the prior art and, hydrogen at the 2-position instead of methyl in the claimed compound. See column 188, Example 21, lines 50-60.

However, in *Ex parte Wiseman*, 98 USPQ 277 (1953), it was held that compounds are rejected over prior art when the difference between the claimed compounds and the compounds of the prior art is two fluorine atoms versus chlorine atoms. The basis of this reasoning is that fluorine and chlorine are both halogen elements from the seventh group of the periodic system and the claimed compound is

thus an analogue, or more properly, an isologue of that disclosed in the prior art. Hence, the compounds are expected to possess similar properties differing only in degree. The invention of Takahashi et al., '514' teach several combinations that would place Applicants invention in possession of the public at the time Applicants invention was filed.

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made since Takahashi et al., teach compounds which are homologous to the claimed compounds. The claimed compounds are so closely related structurally to the homologous compounds of the reference as to be structurally obvious in the absence of any unobvious or unexpected properties. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds are generally expected to have similar properties and have similar utilities. *In re Gyurik*, 596 F. 2d. 1012, 201 USPQ 552 (CCPA) (1979). Therefore, the claimed compounds would have been suggested to one of ordinary skill in the art absent a showing of unobvious or unexpected results.

Claims 1-31 are not rejected over any prior art and are thus, allowable over the cited prior art references.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (703) 305-6889. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the

examiner's supervisor, Joseph K. McKane, can be reached on (703) 308-4537.

The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

EOS
September 19, 2005

for Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1600
Technology Center 1